Mirada Medical Ltd
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
WARREN NJ 07059

September 11, 2020

Re: K202297
Trade/Device Name: Aline Ablation Intelligence
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 12, 2020
Received: August 13, 2020

Dear Mr. Yungvirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

The completed Form FDA 3881 Indications for Use is provided here (page 1 of 1).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202297

Device Name
Aline Ablation Intelligence

Indications for Use *(Describe)*
Aline Ablation Intelligence is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures.
Aline Ablation Intelligence is controlled by the user via a user interface on a workstation.
Aline Ablation Intelligence imports images from CT and MR scanners and facility PACS systems for display and processing during ablation procedures.
Aline Ablation Intelligence is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. Aline Ablation Intelligence is used to assist physicians in confirming ablation zones.
The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

(The following information is in conformance with 21 CFR 807.92)

510(k) Number	K202297
Date of summary:	September 9th 2020
Submitter's name:	Mirada Medical Ltd
Submitter's address:	New Barclay House, 234 Botley Rd, Oxford OX2 0HP. United Kingdom United Kingdom
Submitter's contact:	David Clafton
Telephone number:	+44(0)1865 817600
Device Proprietary Name:	Aline Ablation Intelligence
Device Common Name(s):	Aline Ablation Intelligence
Regulation Number	892.2050
Regulation Name	Picture archiving and communications system.
Regulatory Class	Class II
Primary Product Code	LLZ

Predicate Device

510(k) Number	K150313
Trade Name	Ablation Confirmation (AC)
Manufacturer	NeuWave Medical, Inc.
Device Name	Ablation Confirmation
Regulation Number	892.2050
Regulation Name	Picture archiving and communications system.
Regulatory Class	Class II
Primary Product Code	LLZ

Reference Devices

The following reference devices are used within this submission to support the substantial equivalence discussion regarding performance evaluation. These devices have been selected as they share common features and technological characteristics with the proposed device.

510(k) Number	K102687
Trade Name	Mirada RT

Manufacturer	Mirada Medical Ltd
Device Name	Mirada RT
Regulation Number	892.2050
Regulation Name	Picture archiving and communications system.
Regulatory Class	Class II
Primary Product Code	LLZ

510(k) Number	K130393
Trade Name	Mirada RTX
Manufacturer	Mirada Medical Ltd
Device Name	Mirada RTX
Regulation Number	892.2050
Regulation Name	Picture archiving and communications system.
Regulatory Class	Class II
Primary Product Code	LLZ

510(k) Number	K101228
Trade Name	Mirada XD
Manufacturer	Mirada Medical Ltd
Device Name	Mirada XD
Regulation Number	892.2050
Regulation Name	Picture archiving and communications system.
Regulatory Class	Class II
Primary Product Code	LLZ

5.1 Device Description

Aline Ablation Intelligence 1.0.0, is a stand-alone desktop software application with tools and features designed to assist users in planning ablation procedures as well as tools for evaluating ablation procedure's outcome.

The use environment for Aline Ablation Intelligence is the Operating Room and the hospital healthcare environment such as interventional radiology control room.

Aline Ablation Intelligence has five distinct workflow steps:

- Data assignment
- Tumor segmentation
- Needle planning
- Ablation zone segmentation
- Treatment confirmation

Of these workflow steps two (Tumor Segmentation and Needle Planning) make use of the planning image volume. These workflow steps contain features and tools designed to support the planning of ablation procedures. The other two (Ablation Zone Segmentation, and Treatment Confirmation) make use of the confirmation image volume. These workflow steps contain features and tools

designed to support the evaluation of the ablation procedure's outcome in the confirmation image volume.

Key features of the Aline Ablation Intelligence Software include:

- Workflow steps availability
- Manual and Automated tools for target tissue and ablation zone segmentation
- Overlaying and positioning virtual ablation needles and user-selected estimates of the ablation regions onto the medical images
- Multimodal image fusion and registration
- Compute achieved margins and missed volumes to help the user assess the coverage of the target tissue by the ablation zone
- Data saving and secondary capture generation

The software components provide functions for performing operations related to image display, manipulation, analysis, and quantification, including features designed to facilitate segmentation of the target tissues and ablation zones.

The software system runs on a dedicated workstation and is intended for display and processing, of a Computed Tomography (CT) and/or Magnetic Resonance (MR) image, including contrast enhanced images.

The system can be used on patient data for any patient demographic chosen to undergo the ablation treatment.

Aline Ablation Intelligence uses several algorithms to perform operations to present information to the user in order for them to evaluate the planned and post ablation zones. These include:

- Segmentation post-processing
- Automatic ROI definition for Local Rigid Registration
- Measurement and Quantification

5.2 Indications for Use

Aline Ablation Intelligence is a Computed Tomography (CT) and Magnetic Resonance (MR) image processing software package available for use with ablation procedures.

Aline Ablation Intelligence is controlled by the user via a user interface on a workstation.

Aline Ablation Intelligence imports images from CT and MR scanners and facility PACS systems for display and processing during ablation procedures.

Aline Ablation Intelligence is used to assist physicians in planning ablation procedures, including identifying ablation targets and virtual ablation needle placement. Aline Ablation Intelligence is used to assist physicians in confirming ablation zones.

The software is not intended for diagnosis. The software is not intended to predict ablation volumes or predict ablation success.

5.3 Technical characteristic comparison

Characteristic	Aline Ablation Intelligence	NeuWave – Ablation Confirmation	Equivalence
510(k) number	K202297	K150313	n/a

Classification	Class II. 892.2050 LLZ	Class II. 892.2050 LLZ	n/a
Target Population	The intended patient population of the Aline Ablation Intelligence software is the patient demographic chosen by interventional radiologists to undergo ablation treatment (including patient with soft tissue lesions).	Patient with soft tissue lesions.	Equivalent
Where Used	The application's use environment is the Operating Room and the hospital healthcare environment such as interventional radiology control room.	Ablation Confirmation™ (AC), is a Computed Tomography (CT) image processing software package available as an optional feature for use with the Certus® 140 2.45 GHz Ablation System. AC is controlled by the user via an independent user interface on a second monitor separate from the Certus 140 user interface. All AC processing and viewing is accomplished at the Certus® 140 Ablation System without the physician having to leave the procedure area to utilize separate image processing tools.	Substantially Equivalent
Energy Used and/or Delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	None – software only application. The software application does not deliver or depend on energy delivered to or from patients, this image processing software package is an optional for use with the Certus® 140 2.45 GHz Ablation System	Equivalent
Intended Users	Physicians	Physicians	Equivalent
Design: Supported modalities	CT, MRI.	CT, MRI.	Equivalent
Design: Data Visualization	Window and level, pan, zoom, cross-hairs, slice navigation	Window and level, pan, zoom, cross-hairs, slice navigation	Equivalent

Design: Image Segmentation	Tools for segmenting 3D VOIs, including target tissues and ablation zones.	Tools for segmenting 3D VOIs, including target lesions and ablation zones.	Equivalent
Design: Image registration	Registration of multiple images into a single view.	Registration of multiple images into a single view.	Equivalent
Design: Ablation zone confirmation	Aline Ablation Intelligence can perform a registration of the planning scan, containing the identified target tissue, with the confirmation scan showing the ablation zone. The delineated target tissue on the planning scan is then projected onto the confirmation scan and overlaid onto the delineated ablation zone segmentation. This to help the user in analyzing if the ablation zone covers the target tissue with the desired amount of margin.	AC can then perform a registration of the initial CT scan, containing the identified target, with the final CECT scan containing the segmented ablation zone. The resulting image set includes the ablation zone overlaid onto the initial target lesion segmentation to help physicians determine the technical success (ablation zone covers target lesion with desired amount of margin) of the ablation procedure.	Substantially Equivalent
Design: Save key images to PACS	Key images can be acquired which may be saved back to PACS or any DICOM nodes.	All snapshot taken during procedure are stored to PACS.	Substantially Equivalent
Human Factors	Intended to be used safely and effectively by trained physicians and a human factors engineering process has been undertaken, adhering to IEC 62366-1:2015.	Unknown	Substantially Equivalent
Materials	Not applicable - software device only	Not applicable - software device only	n/a
Biocompatibility	Not applicable - software device only	Not applicable - software device only	n/a
Sterility	Not applicable - software device only	Not applicable - software device only	n/a
Electrical safety	Not applicable - software device only	Not applicable - software device only	n/a
Mechanical Safety	Not applicable - software device only	Not applicable - software device only	n/a

Chemical Safety	Not applicable - software device only	Not applicable - software device only	n/a
Thermal Safety	Not applicable - software device only	Not applicable - software device only	n/a
Radiation Safety	Not applicable - software device only	Not applicable - software device only	n/a
Computer platform & operating system	Microsoft Windows compatible machine. 64-bit Windows 7 and 10.	Installed on the Certus 140 system, OS unknown.	Substantially Equivalent
Labelling	Labelling complies with 21 CFR 801/830	Requirements should be met based on 510(k) submission	Substantially Equivalent
Instructions for Use	Help Guide, Installation Guide, Release Notes	Requirements should be met based on 510(k) submission	Substantially Equivalent

5.4 Substantial Equivalence

When compared to the indications listed for the predicate device and applicable to the proposed device, the proposed device is substantially equivalent to the predicate device.

Both devices provide similar tools with which to register and segment images for planning (pre-treatment) and confirmation (post-treatment).

The key differences between the predicate device and the proposed device is that the proposed device is not indicated for the identification of ablation probes in order to ensure proper ablation placement.

Additionally, the proposed device is indicated for placement of virtual ablation needles on the planning image volumes so to visualize size and location of the ablation regions created by the needles.

The needle planning features of the proposed device support the user in enhancing the evaluation of the needle planning procedure, performed in accordance with its intended use, and do not result in any new potential safety risks.

The above analysis of the characteristics of the Mirada Medical Aline Ablation Intelligence and the Predicate Device demonstrate that the proposed device is substantially equivalent, and the differences do not introduce additional risks that could affect safety or effectiveness.

There are no new indications for use for Aline Ablation Intelligence and therefore by following the FDA guidance document “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”, Aline Ablation Intelligence is determined to be substantially equivalent to the predicate device.

5.5 Performance

Aline Ablation Intelligence is validated and verified against its user needs and intended use by the successful execution of planned performance, functional and algorithmic testing included in this submission.

The results of performance, functional and algorithmic testing demonstrate that Aline Ablation Intelligence meets the user needs and requirements of the device, which are considered to be substantially equivalent to those of the listed predicate device.

Test planning was performed in accordance with standard testing procedures and guidelines as listed in internal development processes.

Human factors testing has been performed in line with Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016 and IEC 62366-1:2015.

Verification and validation testing were carried out as per planned arrangements in the Project Test Plan and Phase Test Plan(s) to ensure that design outputs meet design inputs and that this edition of Aline Ablation Intelligence meets the product acceptance criteria. These are in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "Guidance on Software Contained in Medical Devices" and adherence to the DICOM standard.

Potential risks were analyzed and satisfactorily mitigated in the device design.

Performance testing (Bench) was performed, including on the following features, to ensure that performance and accuracy was as expected:

- Segmentation post-processing Testing
- Automatic ROI definition for Local Rigid Registration Testing
- Measurement and Quantification Testing

Aline Ablation Intelligence 1.0.0 provides functions including linear distance measurements and volumetric measurements. The resolution of the medical image data directly affects the ability of the user to make definitive measurements, especially when the sizes of structures to identify, segment or measure are near the resolution of the image data. The software’s functions are dependent on the user actions as well as on the available information in the provided medical image data.

Segmentation tools provided within Aline Ablation Intelligence 1.0.0 include manual and semi-automated segmentation, and system post-processing of segmentations to remove 2D-holes and/or disconnected 3D regions present. The use of the segmentation tools to achieve a satisfactory delineation of tumor or ablated tissue is a user operation and the clinical accuracy of segmentation is the responsibility of the user and not an Aline Ablation Intelligence function.

Registration tools provided within Aline Ablation Intelligence 1.0.0 include automated local rigid registration within a region of interest around user-segmentations of tumors and ablation zones. Final accuracy of registration is dependent on user assessment and manual modification of the registration prior to acceptance, and not an Aline Ablation Intelligence function.

Measurements of the achieved margins and missed volumes, calculated by comparing the segmentations, are presented by the system following user acceptance of segmentations and registration as clinically accurate. Accuracy of linear distance measures calculated by Aline Ablation Intelligence 1.0.0 are dependent on the image resolution; these are accurate to ¼ of a

voxel width and are reported to 0.1mm precision. Volume calculations by Aline Ablation Intelligence 1.0.0 are dependent on the image resolution; these are at whole-voxel resolution and voxel inclusion/exclusion is determined by whether the voxel center is inside or outside the displayed contour. Volume is reported to 0.001cm3 precision.

It is the responsibility of the user to determine if the results of image visualization are satisfactory and allow the accurate use of the functions provided.

5.6 Standards and guidelines

Aline Ablation Intelligence complies to the following FDA recognized standards:

- IEC 62304:2006+A1:2015
- IEC 62366-1:2015
- NEMA PS 3.1 - 3.20 (2016) DICOM 3.0

The following other Standards were used during development of Aline Ablation Intelligence:

- ISO 14971:2012
- ISO 13485:2016

The following guidelines were used during development of Aline Ablation Intelligence:

- How to Prepare a Traditional 510(k)" and "eCopy Program for Medical Device submissions" dated October 10, 2013.
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k), July 28, 2014
- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, December 20, 2019.
- Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2, 2014.
- Guidance for the content of premarket submissions for software contained in medical devices, May 11, 2005
- Format for Traditional and Abbreviated 510(k)s, September 13, 2019.

5.7 Conclusion

In conclusion, performance testing demonstrates that Aline Ablation Intelligence is substantially equivalent to, and performs at least as safely and effectively as, the listed predicate device. Aline Ablation Intelligence meets requirements for safety and effectiveness and does not introduce any new potential safety risks.